

Appendix A

**Third Party-Produced Documents Subject to
Stipulation D.2.**

Appendix A: Third Party-Produced Documents Subject to Stipulation D.2

Description	Date	Bates
EndoWrist Service Procedure, by Greg Fiegel	04/25/2019	REBOTIX162404
Traditional 510(k) Notification Re-manufactured EndoWrists (Rebotix)	12/18/2014	REBOTIX170421
Letter from R. Burke to Dr. Wen re: Rebotix, LLC's intent to withdraw 510(k) Premarket Notification	12/17/2015	REBOTIX171076
Letter from M. Trumbore (FDA) to C. Gibson re: remanufacturing the da Vinci S EndoWrist Instruments	11/16/2021	REBOTIX175417
Email from R. Ferreira to C. Parker and T. Einwechter re: Restore Robotics / AHCP Agreement	07/09/2019	Restore-00010131
Excerpted 510(k) Premarket Notification	12/15/2020	Restore-00086907
Email from R. Ferreira to R. Chudzik re: K210478 is on Hold Pending Your Response	03/30/2021	AHP000526
Email from R. Chudzik to C. Wolfbrandt FW: K210478 - AINN Follow-Up Meeting	04/14/2021	AHP000521
Email from R. Chudzik to S. Peri and R. Ferreira RE: [EXTERNAL] RE: K210478 is on Hold Pending Your Response	04/22/2021	AHP002130
510(k) Premarket Notification	5/5/2021	AHP002395
510(k) Premarket Notification Additional Information re K210478	05/27/2021	Restore-00087401
Email from R. Chudzik to K. May, C. Parker, and R. Ferreira Fwd: [EXTERNAL] Request for an extension of time for 510k (K210478) AI	09/29/2021	Restore-00096294
Email from R. Chudzik to R. Ferreira FW: [EXTERNAL] K210478/S001 is on Hold Pending Your Response	10/01/2021	Restore-00104982
Email from R. Ferreira to C. Parker et al. FW: [EXTERNAL] K210478/S002 Review Complete	10/01/2022	Restore-00099136
Email from R. Ferreira to T. Milano, S. Fitzgibbons, and T. Einwechter FW: [EXTERNAL] RE: [EXTERNAL] K210478/S001 is on Hold Pending Your Response	05/24/2022	Restore-00112143

Email from R. Chudzik to K. May, C. Parker, and R. Ferreira RE: [EXTERNAL] PRE SUB km	06/06/2022	Restore-00091435
Email from R. Chudzik to R. Ferreira, K. May, and C. Parker Re: [EXTERNAL] RE: [EXTERNAL] K210478/S001 is on Hold Pending Your Response	09/16/2022	Restore-00091370
Email from Restore Robotics Repairs Customer Service (K. May) to C. Parker and M. Vautrot FW: Endowrist agreement	10/08/2019	Restore-00010600
Email from M. Wen to R. Burke Re: K143619/S002 is on Hold Pending Your Response	06/23/2015	REBOTIX171058
Email from R. Burke to J. Morrison Fwd: Rebotix AI Letter Conference Call Follow Up	07/09/2015	REBOTIX077729
Distributor Agreement between Rebotix and Restore	10/13/2018	REBOTIX050713
RAI FDA Letter K143619 S002 Deficiencies	06/23/2015	REBOTIX171030
Email from G. Papit to A. Lee et al. Re: [EXTERNAL] Rebotix Repair, LLC re Document Number CPT2000126	07/22/2022	REBOTIX175839
Email from A. Lee to R. Ferreira RE: [EXTERNAL] RE: [EXTERNAL] K210478/S001 is on Hold Pending Your Response	06/30/2022	Restore-00086093
Email from R. Ferreira to R. Chudzik FW: 510k Endowrists	03/08/2019	AHP000147
Email from R. Ferreira to R. Chudzik Re: name and address for contract and billing	07/13/2020	AHP004826
Email from R. Ferreira to J. Barnett and M. Vautrot Fw: Fwd: Da Vinci Robot Savings Opportunity	05/02/2019	AHP000490
Email with attachment from R. Ferreira to J. Barnett et al. FW: Restore Robotics Follow Up	07/12/2019	Restore-00010153
Process Verification and Validation (PV&V) Report: Intuitive Da Vinci EndoWrist Monopolar Curved Scissors	01/15/2021	AHP002680
Email from R. Chudzik to S. Peri and R. Ferreira RE: [EXTERNAL] RE: K210478 is on Hold Pending Your Response	04/15/2021	AHP002062
Memorandum from R. Arkin to K. May and C. Parker Re: Discussions with FDA about EndoWrist counter	04/09/2019	ACG000006

Email with attachment from R. Ferreira to C. Parker et al. FW: K210478 Acknowledgement Notification	02/19/2021	AHP000524
Email with attachment from C. Gibson to C. Parker et al. re: Scanner Software	06/05/2018	REBOTIX020786
Email from C. Gibson to K. May et al. Re: Service related Questions	07/03/2018	REBOTIX038847
Email from K. May to S. Hamilton and C. Parker RE: Service related Questions	08/21/2018	REBOTIX040758
Email from G. Fiegel to S. Hamilton, G. Papit, and D. Mixner Re: MEMS opportunity - request for a Zoom video call	10/09/2018	REBOTIX043217
Email from S. Hamilton to C. Gibson et al. Re: PRICING	10/18/2018	REBOTIX043680
Email from C. Gibson to K. Johnson re: Marin Response Document	12/04/2019	REBOTIX082658
EndoWrist (FullLength).MOV	10/15/2018	REBOTIX175327
Email from G. Fiegel to G. Smith et al. RE: MEMS opportunity - request for a ZOOM call	10/18/2018	REBOTIX167237
Email from G. Papit to G. Smith et al. Re: MEMS opportunity - request for a ZOOM call	10/19/2018	REBOTIX167361
Letter from Restore Robotics to "Kathy" re: Liability, Warranty and Sterilization	02/01/2019	Restore-00000792
Intuitive Publication, "FAQs for Unauthorized Reprogrammed Instruments"	06/15/2017	Restore-00001954
Email from C. Parker to J. Colletti and J. Sheehy re: FAQ doc	06/20/2019	Restore-00002649
Email from C. Parker to C. Gibson and G. Fiegel FW: Endowrist - No repair	07/15/2019	Restore-00003181
Email from K. May to C. Parker and B. May RE: TEST - da Vinci Endowrist and Accessories at significant savings	08/12/2019	Restore-00007579
Email with attachment from M. King to C. Parker, R. Ferreira, and T. Einwechter re: Signed MOU Restore Robotics	01/18/2019	Restore-00009029
Email from Ferreira to C. Parker et al. Re: Reprogrammed da Vinci Instruments - Crescent City Patient Safety Implications Letter	09/18/2019	Restore-00010560
Email from J. Barnett to C. Parker FW: Restore Robotics Follow Up	07/09/2019	Restore-00015498

Email with attachments from C. Parker to K. May FW: sterilization response doc	01/15/2019	Restore-00016815
Email with attachment from C. Parker to K. May and M. Vautrot FW: DaVinci	05/13/2019	Restore-00017039
Email with attachment from C. Parker to billing@reach3d.net re: Brochures	10/12/2018	Restore-00018745
Email with attachments from C. Parker to J. Winkler re: Restore Robotics	11/30/2018	Restore-00022922
Email from G. Posdal to C. Parker re: Revised NDA	08/26/2020	Restore-00058241
Email from G. Terrell to C. Parker Re: Univ of Cincinnati	06/27/2018	Restore-00061148
Email from J. Barnett to R. Ferreira, C. Parker RE: Restore Robotics Follow Up	07/17/2019	Restore-00061400
Email from K. May to C. Parker and B. May RE: TEST - da Vinci Endowrist and Accessories at significant savings	08/12/2019	Restore-00074134
Email and attachment from K. May to C. Parker re: import into USA	08/20/2018	Restore-00074345
Email with attachment from C. Parker to E. Dickens re: MOU -Dr. Eugene Dickens- Restore Robotics revised 02232020.docx	02/23/2020	Restore-00076071
Email with attachments from R. Chudzik to A. Lee, M. Trumbore, and R. Ferreira RE: [EXTERNAL] RE: [EXTERNAL] K210478/S001 is on Hold Pending Your Response	04/14/2022	Restore-00090136
Email from R. Ferreira to A. Lee et al. Re: [EXTERNAL] RE: [EXTERNAL] K210478/S001 is on Hold Pending Your Response	08/2/2022	Restore-00091502
Email from K. May to K. Johnson and C. Parker re: summary of last instrument received	05/20/2022	Restore-00094610
Email with attachments from K. May to C. Parker FW: Robotic Arms	04/26/2022	Restore-00094694
Email from K. May to K. Zak et al. RE: Xi Arms Sent In	12/29/2021	Restore-00094766
Email from K. May to K. Johnson and C. Parker FW: Recovery Program	11/01/2021	Restore-00094783
Email from R. Chudzik to K. May et al. Fwd: [EXTERNAL] Re: K210478 - Iconocare Health 510(k) Submission	03/19/2021	Restore-00095403
Email with attachments from R. Chudzik to K. May et al. FW: K210478 -	09/24/2021	Restore-00095711

Additional Information Needed for EMC and Software		
Email from R. Chudzik to K. May, C. Parker, and R. Ferreira RE: [EXTERNAL] RE: AINN #2	10/08/2021	Restore-00096308
Email from R. Ferreira to C. Parker et al. FW: K210478/S001 Acknowledgement Notification	08/16/2021	Restore-00098414
Letter from M. Trumbore to K. Gunjal Re: K214095	08/15/2022	Restore-00137833
Email with attachment from C. Parker to K. Johnson re: NDA - 091420.pdf	09/14/2020	Restore-00057179
Email with attachment from K. May to C. Parker, S. Hamilton, and G. Fiegel re: Signed agreement	10/12/2018	REBOTIX000267
Email from G. Papit to A. Moltz Re: FW: Warranty & Insurance Policy	06/28/2019	REBOTIX057698_001
Letter from M. Shulman to R. Burke re: K143619 - S2 Submission Acknowledgment	04/09/2015	REBOTIX077545_001
Email from R. Burke to J. Bua and J. Morrison RE: Meeting At Rebotix	08/11/2015	REBOTIX077799_001
Email from C. Gibson to K. May Re: Endowrist agreement	10/08/2019	REBOTIX080214
Rebotix, LLC Management Review Meeting Minutes	05/04/2015	REBOTIX081742_001
Email from J. Herdman to J. Freehling et al. Re: [External] October Rebotix Repair Savings	11/12/2019	REBOTIX082118
Rebotix Meeting Agenda	10/10/2014	REBOTIX084240_001
Rebotix Document Approval Form, "Risk Management Report" prepared by R. Burke	02/13/2015	REBOTIX084870_001
Email from L. Davis to G. Fiegel and G. Papit RE: Hello from Bartow	02/18/2020	REBOTIX084983
Email from R. Burke to J. Morrison et al. re: Life Test Reports	12/15/2014	REBOTIX087644_001
Letter from M. Shulman to R. Burke re: 510(k) Acknowledgment (K143619)	12/19/2014	REBOTIX128997_001
Risk Management Report: Remanufactured Surgical EndoWrists	02/11/2016	REBOTIX133038_001
Letter from B. White to D. Mixner	12/10/2015	REBOTIX139042_001
Notice of Termination of Distributor Agreement between Rebotix Repair, LLC and Restore Robotics Repairs, LLC	07/08/2019	REBOTIX144629_001

Email from C. Gibson to G. Fiegel FW: Request for More Information on Rebotix Repair Repairing/Service Activities	06/25/2020	REBOTIX146948 001
Module (F) Shelf Life	12/14/2014	REBOTIX169166
Module (K) Performance Characteristics (In Vitro Diagnostic Only)	12/14/2014	REBOTIX169167
Module (H) Software	12/12/2014	REBOTIX169168
Module (I) EMC and Electrical Safety	12/14/2014	REBOTIX169360
Module (E) Sterilization	12/14/2014	REBOTIX169504
Module (D) Proposed Labeling	12/14/2014	REBOTIX169588
Module (G) Biocompatibility	12/14/2014	REBOTIX169683
Module (C) Substantial Equivalence Discussion	12/17/2014	REBOTIX169926
Module (B) Device Description	12/14/2014	REBOTIX169947
Module (J) Performance Data	12/15/2014	REBOTIX170053
Final Report Technical File Review acc. Sample Plan for Rebotix, LLC Electrosurgical Endowrists	03/03/2021	REBOTIX162889
Risk Management Plan Remanufactured Surgical Endowrists	12/22/2015	REBOTIX123792
December FMEA For Use w/ Verification Check Off	12/05/2014	REBOTIX084174
Email from L. Davis to G. Fiegel RE: Invoice 26775 from Rebotix Repair LLC	02/12/2020	REBOTIX084679
Email from G. Papit to C. Gibson and G. Fiegel Fw: THOMAS	01/29/2020	REBOTIX084240
Document Approval Form, "Life Test Worst Case Model Analysis" prepared by J. Morrison	12/18/2014	REBOTIX146770
Email from C. Gibson to C. Parker et al. re: Rebotix Meeting	05/31/2018	Restore-00060361
Email from R. Chudzik to B. Joseph and C. Wolfbrandt Fwd: [EXTERNAL] Re: K210478 - Iconocare Health 510(k) Submission	08/18/2021	Restore-00106446
Email from R. Chudzik to C. Wolfbrandt and B. Joseph Re: [EXTERNAL] RE: K21-478 is on Hold Pending Your Response	09/09/2021	Restore-00132582
Email from R. Ferreira to R. Chudzik FW: [EXTERNAL] RE: [EXTERNAL] K210478/S001 Is on Hold Pending Your Response	12/21/2021	Restore-00109056
Email from R. Chudzik to T. Fleming and A. Babcock FW: [EXTERNAL] Re:	3/22/2021	AHP000853

K210478 -Iconocare Health 510(k) Submission		
EndoWrist Monopolar Curved Scissors Instrument Description of Device	05/05/2021	AHP002829
Innovative Health Biocompatibility Evaluation of the Intuitive Da Vinci EndoWrist Monopolar Curved Scissor Test Report TR-0681 (including attachments)	05/05/2021	AHP002448
Email from G. Fiegel to K. May and C. Parker RE: purchased items	10/02/2018	Restore-00007938
Email from A. Dalmau to L. Thording et al. Re: Meeting Request regarding your daVinci Surgical System	08/08/2019	Restore-00010382
Email from K. May to G. Fiegel, C. Parker, and R. Mixner RE: Agenda	10/01/2018	Restore-00013881
Email from S. Hamilton to G. Fiegel and M. Vaultrot Re: Support Request - document Review	10/29/2018	Restore-00027151
Email from C. Parker to M. Vautrot Fwd: Rebotix	04/10/2019	Restore-00028165
Email with attachment from C. Parker to C. Parker Fwd: Restore budget	07/08/2020	Restore-00064505
Email from C. Parker to M. Vautrot Re: INTERESTING INTUITIVE STAT	05/10/2018	Restore-00067714
K210478 Indications for Use	04/05/2022	Restore-00137830
Substantial equivalency letter from M. Trumbore to R. Ferreira Re: K210478	09/30/2022	Restore-00137831
De Novo Classification Request for the Versius® Surgical System by CMR Surgical Limited	n/a	CMR-00000001
CMR Surgical Limited and [CUSTOMER] Supply and Services Agreement	n/a	CMR-00000229
Senhance® US Articulating Brochure	2024	https://www.asensus.com/sites/default/files/2024-01/Articulating%20Brochure_US.pdf
Why Healthcare Needs to Prioritize Remanufactured Robotic Instruments	09/11/2023	https://encoremdr.com/videos/; https://youtu.be/wJANFrIRUx4
Transparency & Accountability in Surgical Instrument Repair	01/23/2024	https://encoremdr.com/videos/; https://youtu.be/03BMvt5k004
The Need to Drive Change	09/11/2023	https://encoremdr.com/videos/; https://youtu.be/AMHnhSUSTIY
Axius IFU - FlexDex Surgical 8mm Needle Driver Instructions for Use	08/06/2024	https://flexdex.com/ifu/